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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/541,502	12/23/2005	Scott Eugene Conner	2947.1009-005	8241
21005 7590 11/26/2007 HAMILTON, BROOK, SMITH & REYNOLDS, P.C. 530 VIRGINIA ROAD P.O. BOX 9133 CONCORD, MA 01742-9133			EXAMINER NOLAN, JASON MICHAEL	
			ART UNIT 1626	PAPER NUMBER
			MAIL DATE 11/26/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/541,502	<b>Applicant(s)</b> CONNER ET AL.	
	<b>Examiner</b> Jason M. Nolan, Ph.D.	<b>Art Unit</b> 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 23 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-11, 17, 19, 20, 25, 28, 29, 35, 38, 39, 44, 46, 50, 53-55, 101 and 108 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-11, 17, 19, 20, 25, 28, 29, 35, 38, 39, 44, 46, 50, 53-55, 101 and 108 are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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### **DETAILED ACTION**

**Claims 1-11, 17, 19, 20, 25, 28, 29, 35, 38, 39, 44, 46, 50, 53-55, 101, & 108** are pending in the instant application. **Claims 2, 9, 11, 17, 20, 25, 29, 35, 39, 44, 50, 53, 101, & 108** are currently amended. **Claims 12-16, 18, 21-24, 26, 27, 30-34, 36, 37, 40-43, 45, 47-49, 51, 52, 56-100, 102-107, & 109-114** are canceled.

### ***Election/Restrictions***

Restriction is required under 35 U.S.C. § 121 and § 372.

**Claims 1-11, 17, 19, 20, 25, 28, 29, 35, 38, 39, 44, 46, 50, 53-55, 101, & 108** are drawn to more than one inventive concept (as defined by PCT Rule 13), and accordingly, a restriction is required according to the provision of PCT Rule 13.2.

PCT Rule 13.2 states that the international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept (requirement of unity of invention).

PCT Rule 13.2 states unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features.

Annex B, Part 1 (b), provides that "special technical features" mean those technical features, which, as a whole, define a contribution over the prior art.

Annex B, Part 1 (e), provides combinations of different categories of claims and states:

"The method for determining unity of invention under Rule 13 shall be construed as permitting, in particular, the inclusion of any one of the following combinations of claims of different categories in the same international application:

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(i) in addition to an independent claim for a given product, an independent claims for a process specially adapted for the manufacture of the said product, and an independent claim for use of the said product, or

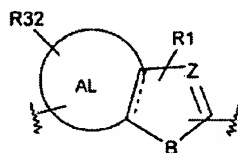
(ii) in addition to an independent claim for a given process, an independent claim for an apparatus or means specially designed for carrying out the said process, or

(iii) in addition to an independent claim for a given product, and independent claim for a process specially adapted for the manufacture of the said product, and an independent claim for an apparatus or means specially designed for carrying out the said process,..."

This application contains the following inventions or groups of inventions that are not so linked as to form a single general inventive concept under PCT Rule 13.1.

**Group 1:** Claims 1-11, 17, 19, 20, 25, 28, 29, 35, 38, 39, 44, 46, 50, 53-55, 101, & 108, drawn to compounds according to the formula in **Claim 1** wherein

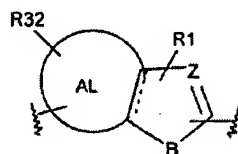
**Z4 = N and T1 =**



and methods of using them.

**Group 2:** Claims 1-11, 17, 19, 20, 25, 28, 29, 35, 38, 39, 44, 46, 50, 53-55, 101, & 108, drawn to compounds according to the formula in **Claim 1** wherein

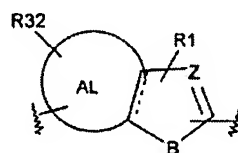
**Z4 = S and T1 =**



and methods of using them.

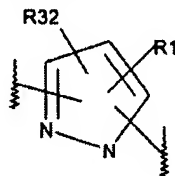
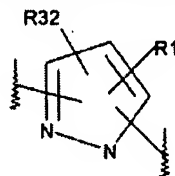
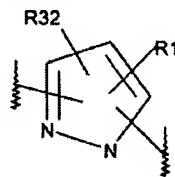
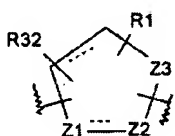
**Group 3:** Claims 1-11, 17, 19, 20, 25, 28, 29, 35, 38, 39, 44, 46, 50, 53-55, 101, & 108, drawn to compounds according to the formula in **Claim 1** wherein

**Z4 = O and T1 =**



and methods of using them.

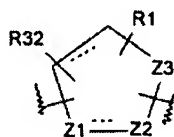
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**Group 4: Claims 1-11, 17, 19, 20, 25, 28, 29, 35, 38, 39, 44, 46, 50, 53-55, 101, &****108, drawn to compounds according to the formula in Claim 1 wherein****Z4 = N and T1 =****and methods of using them.****Group 5: Claims 1-11, 17, 19, 20, 25, 28, 29, 35, 38, 39, 44, 46, 50, 53-55, 101, &****108, drawn to compounds according to the formula in Claim 1 wherein****Z4 = S and T1 =****and methods of using them.****Group 6: Claims 1-11, 17, 19, 20, 25, 28, 29, 35, 38, 39, 44, 46, 50, 53-55, 101, &****108, drawn to compounds according to the formula in Claim 1 wherein****Z4 = O and T1 =****and methods of using them.****Group 7: Claims 1-11, 17, 19, 20, 25, 28, 29, 35, 38, 39, 44, 46, 50, 53-55, 101, &****108, drawn to compounds according to the formula in Claim 1 wherein****Z4 = N and T1 =****and methods of using them.**

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**Group 8:** Claims 1-11, 17, 19, 20, 25, 28, 29, 35, 38, 39, 44, 46, 50, 53-55, 101, & 108, drawn to compounds according to the formula in **Claim 1** wherein

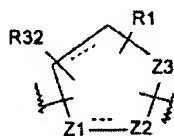
**Z4 = S and T1 =**



and methods of using them.

**Group 9:** Claims 1-11, 17, 19, 20, 25, 28, 29, 35, 38, 39, 44, 46, 50, 53-55, 101, & 108, drawn to compounds according to the formula in **Claim 1** wherein

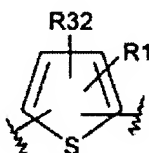
**Z4 = O and T1 =**



and methods of using them.

**Group 10:** Claims 1-11, 17, 19, 20, 25, 28, 29, 35, 38, 39, 44, 46, 50, 53-55, 101, & 108, drawn to compounds according to the formula in **Claim 1** wherein

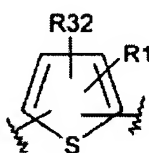
**Z4 = N and T1 =**



and methods of using them.

**Group 11:** Claims 1-11, 17, 19, 20, 25, 28, 29, 35, 38, 39, 44, 46, 50, 53-55, 101, & 108, drawn to compounds according to the formula in **Claim 1** wherein

**Z4 = S and T1 =**

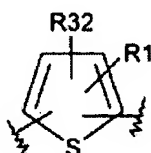


and methods of using them.

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**Group 12:** Claims 1-11, 17, 19, 20, 25, 28, 29, 35, 38, 39, 44, 46, 50, 53-55, 101, & 108, drawn to compounds according to the formula in **Claim 1** wherein

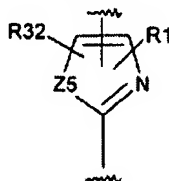
**Z4** = O and **T1** =



and methods of using them.

**Group 13:** Claims 1-11, 17, 19, 20, 25, 28, 29, 35, 38, 39, 44, 46, 50, 53-55, 101, & 108, drawn to compounds according to the formula in **Claim 1** wherein

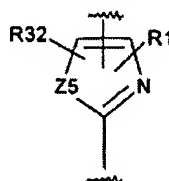
**Z4** = N and **T1** =



and methods of using them.

**Group 14:** Claims 1-11, 17, 19, 20, 25, 28, 29, 35, 38, 39, 44, 46, 50, 53-55, 101, & 108, drawn to compounds according to the formula in **Claim 1** wherein

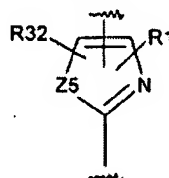
**Z4** = S and **T1** =



and methods of using them.

**Group 15:** Claims 1-11, 17, 19, 20, 25, 28, 29, 35, 38, 39, 44, 46, 50, 53-55, 101, & 108, drawn to compounds according to the formula in **Claim 1** wherein

**Z4** = O and **T1** =

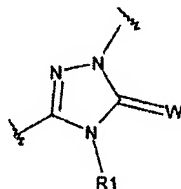


and methods of using them.

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**Group 16:** Claims 1-11, 17, 19, 20, 25, 28, 29, 35, 38, 39, 44, 46, 50, 53-55, 101, & 108, drawn to compounds according to the formula in **Claim 1** wherein

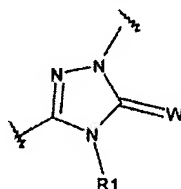
**Z4** = N and **T1** =



and methods of using them.

**Group 17:** Claims 1-11, 17, 19, 20, 25, 28, 29, 35, 38, 39, 44, 46, 50, 53-55, 101, & 108, drawn to compounds according to the formula in **Claim 1** wherein

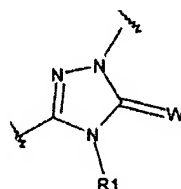
**Z4** = S and **T1** =



and methods of using them.

**Group 18:** Claims 1-11, 17, 19, 20, 25, 28, 29, 35, 38, 39, 44, 46, 50, 53-55, 101, & 108, drawn to compounds according to the formula in **Claim 1** wherein

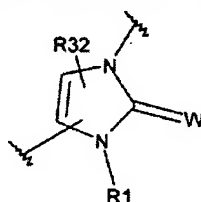
**Z4** = O and **T1** =



and methods of using them.

**Group 19:** Claims 1-11, 17, 19, 20, 25, 28, 29, 35, 38, 39, 44, 46, 50, 53-55, 101, & 108, drawn to compounds according to the formula in **Claim 1** wherein

**Z4** = N and **T1** =



and methods of using them.

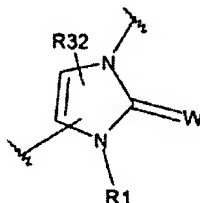


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**Group 20:** Claims 1-11, 17, 19, 20, 25, 28, 29, 35, 38, 39, 44, 46, 50, 53-55, 101, & 108, drawn to compounds according to the formula in **Claim 1** wherein

**Z4 = S and T1 =**

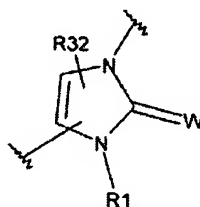
and methods of using them.



**Group 21:** Claims 1-11, 17, 19, 20, 25, 28, 29, 35, 38, 39, 44, 46, 50, 53-55, 101, & 108, drawn to compounds according to the formula in **Claim 1** wherein

**Z4 = O and T1 =**

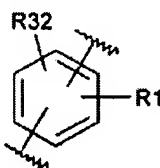
and methods of using them.



**Group 22:** Claims 1-11, 17, 19, 20, 25, 28, 29, 35, 38, 39, 44, 46, 50, 53-55, 101, & 108, drawn to compounds according to the formula in **Claim 1** wherein

**Z4 = N and T1 =**

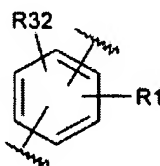
and methods of using them.



**Group 23:** Claims 1-11, 17, 19, 20, 25, 28, 29, 35, 38, 39, 44, 46, 50, 53-55, 101, & 108, drawn to compounds according to the formula in **Claim 1** wherein

**Z4 = S and T1 =**

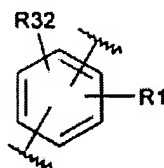
and methods of using them.



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**Group 24:** Claims 1-11, 17, 19, 20, 25, 28, 29, 35, 38, 39, 44, 46, 50, 53-55, 101, & 108, drawn to compounds according to the formula in **Claim 1** wherein

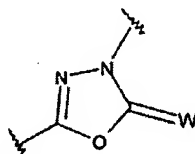
**Z4** = O and **T1** =



and methods of using them.

**Group 25:** Claims 1-11, 17, 19, 20, 25, 28, 29, 35, 38, 39, 44, 46, 50, 53-55, 101, & 108, drawn to compounds according to the formula in **Claim 1** wherein

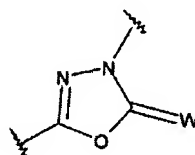
**Z4** = N and **T1** =



and methods of using them.

**Group 26:** Claims 1-11, 17, 19, 20, 25, 28, 29, 35, 38, 39, 44, 46, 50, 53-55, 101, & 108, drawn to compounds according to the formula in **Claim 1** wherein

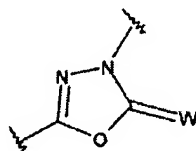
**Z4** = S and **T1** =



and methods of using them.

**Group 27:** Claims 1-11, 17, 19, 20, 25, 28, 29, 35, 38, 39, 44, 46, 50, 53-55, 101, & 108, drawn to compounds according to the formula in **Claim 1** wherein

**Z4** = O and **T1** =



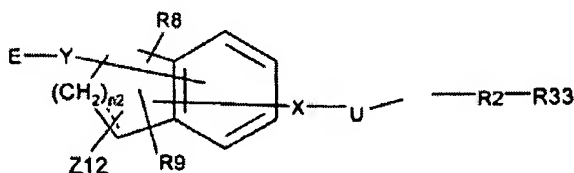
and methods of using them.

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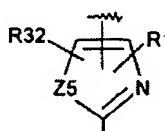
The claims herein lack unity of invention under PCT Rules 13.1 and 13.2 because, pursuant to 37 C.F.R. § 1.475(a) **Group 1 - Group 27** lack unity of invention since, under 37 CFR § 1.475:

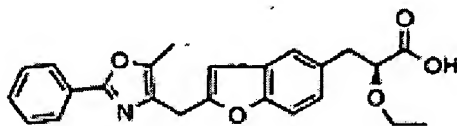
Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical feature among those inventions involving one or more of the same or corresponding special technical features...those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

The structural moiety common to **Group 1 – Group 27** is:



**NOTE: Z4 and T1** are missing because they are not common to all Groups.

This technical feature is not a special technical feature, because it fails to define a contribution over the prior art (see *Rami et al. Exp. Opin. Ther. Patents* **2000**, 10(5), 623-634; see IDS). The compound shown below (5 Pfizer) anticipates the formula of **Claim 1** wherein  $E = CR^3R^4A$ ;  $R^3 = OAk$ ;  $R^4 = H$ ;  $A = C_0$ -alkylcarboxyl;  $Y = C$ ;  $Z^4 = O$ ;  $n_2 = 1$ ;  $R^8$ ,  $R^9$ , &  $Z^{12} = H$ ;  $X = \text{bond}$ ;  $U = CH_2$ ;  $T^1 =$  ;  $Z^5 = O$ ;  $R^1 = CH_3$ ;  $R^{32} = H$ ;  $R^2 = \text{bond}$ ; and  $R^{33} = Ph$ .



**5 Pfizer**

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Therefore, **Claims 1-11, 17, 19, 20, 25, 28, 29, 35, 38, 39, 44, 46, 50, 53-55, 101, & 108** are not so linked as to form a single general inventive concept and there is a lack of unity of invention.

The variables vary extensively and when taken as a whole result in vastly different compounds. Additionally, the vastness of the claimed subject matter and the complications in understanding the claimed subject matter impose a serious burden on the search and examination of the claimed subject matter.

Therefore, since the claims do not relate to a single general inventive concept under PCT Rule 13.1 and lack the same or corresponding special technical features, the claims lack unity of invention and should be limited to a product or a method of use.

Furthermore, with respect to **Group 1 – Group 27**, even if unity of invention under 37 CFR 1.475(a) is not lacking, under 37 CFR 1.475(b) a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations:

- (1) A product and a process specially adapted for the manufacture of said product; or
- (2) A product and process of use of said product; or
- (3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or
- (4) A process and an apparatus or means specially designed for carrying out the said process; or
- (5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specially designed for carrying out the said process.

Moreover, according to 37 CFR 1.475(c),

If an application contains claims to more or less than one of the combinations of categories of invention set forth in paragraph (b), unity of invention might not be present.

In the instant case the claims are drawn to more than a product and a method of use, and according to 37 CFR 1.475(e),

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The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim.


As a result, the claims lack unity of invention and applicant is required to elect a single invention.

### ***Telephone Inquiry***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jason M. Nolan, Ph.D.** whose telephone number is **(571) 272-4356** and electronic mail is **Jason.Nolan@uspto.gov**. The examiner can normally be reached on Mon - Fri (9:00 - 5:30PM). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph M<sup>c</sup>Kane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Jason M. Nolan, Ph.D.  
Examiner  
Art Unit 1626

  
REBECCA ANDERSON  
PRIMARY EXAMINER

Joseph K. M<sup>c</sup>Kane  
Supervisory Patent Examiner  
Art Unit 1626  
Date: November 16, 2007